APR 3 0 2012

VALMED
SWISS TECHNOLOGY

A. 510(k) Summary as Required by Section 807.92(c)

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7. Date Prepared/Finalized

22 July 2011/Finalized 23 April 2012

8. Name of Device

Trade Name: ***SWISS$_{STIM}$***
Common Name: Battery-powered device for transcutaneous nerve and neuromuscular electro-stimulation
Classification Name: Panel/Product Code/Regulation: 89 IPF CFR 890.5850 and subsequent Panel/Product Code/Regulation: 88 GZJ, 882.5890

9. Predicate Devices

This device is substantially equivalent to the following legally marketed devices:

P4-PHYSIO (K022175), and Styline 882 (K092448)

10. Indications for Use

The Indications for Use for the ***SWISS$_{STIM}$*** are shown below:

Indications for EMS use are:

- Prevention or retardation of muscle disuse atrophy
- Relaxation of muscle spasms
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or improving range of motion of extremities

Indications for TENS use are:

- Symptomatic relief and management of chronic, intractable pain, and
- Adjunctive treatment for post-surgical and post-trauma acute pain

11. Device Summary

SWISS$_{STIM}$ is a battery-powered device for transcutaneous nerve and neuromuscular electro-stimulation. It has two channels (outputs) of stimulation, each with independent intensity control. The unit delivers synchronous, low voltage stimulation impulses at both of its outputs. The stimulation output voltage waveforms are in form of trains of monophasic, rectangular impulses. Such waveform character is true, when the outputs are connected to any resistor in a range from 100 Ω to 10,000 Ω.

The EMS mode of this device has four different stimulation programs. The medical professional or patient under medical supervision can select any of these four stimulation programs, as appropriate for their treatment objectives. For each stimulation program, the medical professional or patient selects the desired phases of the stimulation programs as well as the stimulation duration; the impulse frequencies and impulse durations are different and all are preset at the factory.

There are no user accessible controls that can change either the frequency or impulse duration during a treatment. The user accessible controls are the ON/OFF button, the SELECT button and the two (2) buttons that control menu access and intensity levels for the 2 independent channels. The stimulus is a low voltage, low frequency, rectangular waveform.

The TENS mode of this device has ten (10) programs. The TENS mode is what has been added to this device and therefore modifies the Indications for Use from the predicate device, K022175. The TENS mode is controlled in the same fashion as the EMS mode of the ***SWISS$_{STIM}$***.

The device is housed in a plastic enclosure and is powered by four (4) AAA batteries. Accessories include output cables, batteries, User's Manual, storage case and electrodes. There is no provision for an AC adapter and the unit cannot be connected to any AC electrical power circuit.

From a technical perspective, the *SWISS$_{STIM}$* delivers stimulation pulses of 50v (peak value) ± 10% onto 500Ω at maximum settings, which corresponds to 100 mA (peak value) current intensity. The impulse frequencies produced by the device are in a range of 1 Hz to 120 Hz, depending on the choice of stimulation program. The voltage waveforms are rectangular monophasic with duration time from 20 µs to 1000 µs. The current impulses are monophasic on 500 Ω load. The tetanization stimulation signal includes ramp, which slowly increases the contraction intensity during treatments.

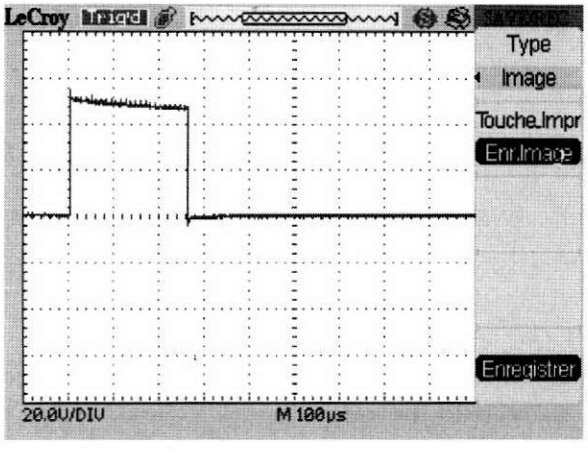
The EMS function is used as a therapeutic tool, specifically for rehabilitation purposes as noted in the Indications for Use (please see Section B). An example is prevention of disuse muscle atrophy that may occur after musculoskeletal injuries such as damage to bones, joints, muscles, ligaments and tendons. The TENS functions address pain mitigation, whether chronic or acute pain; TENS is a non-invasive, safe nerve stimulation intended to reduce such pain. A number of systematic reviews or meta-analyses have confirmed TENS effectiveness for postoperative pain, osteoarthritis, and chronic musculoskeletal pain.

12. Technological Summary

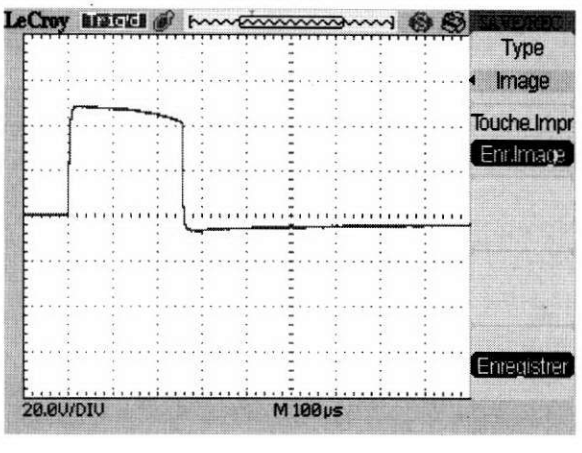
The *SWISS$_{STIM}$* technical characteristics are similar to the predicate devices in design, materials and energy source. A summary of these characteristics is provided below:

Load: 500 ohms

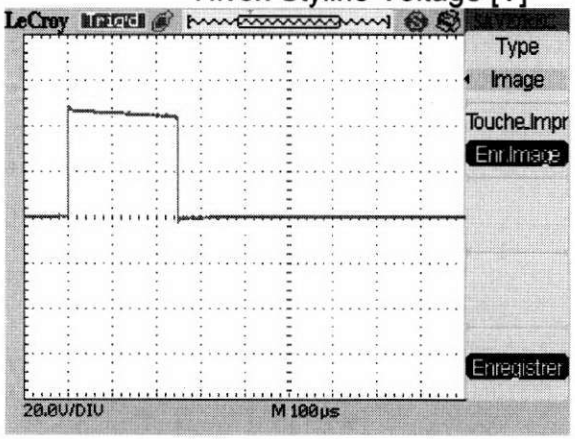
SwissStim Voltage [V]



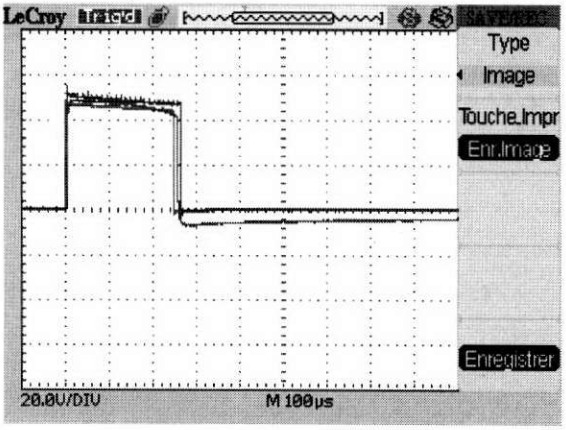
P4 Physio Voltage [V]



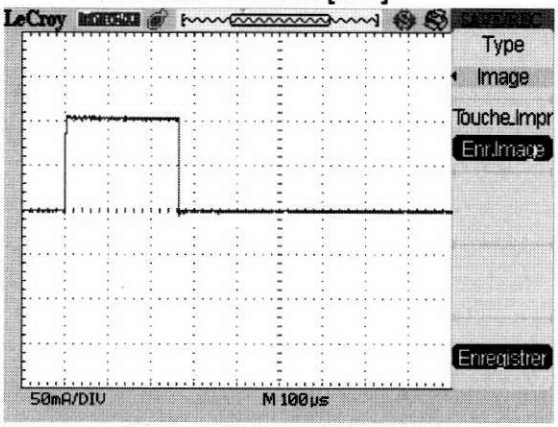
Hivox Styline Voltage [V]



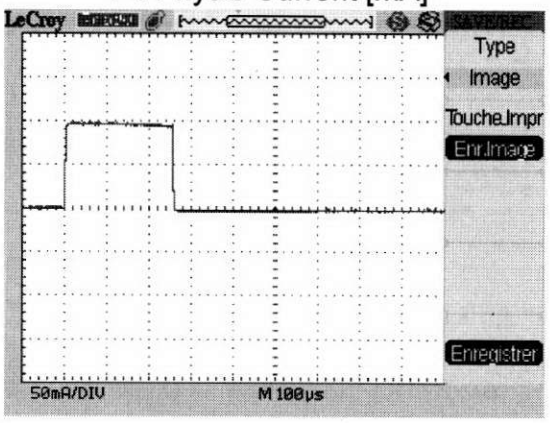
Comparison of All Devices Voltage [V]



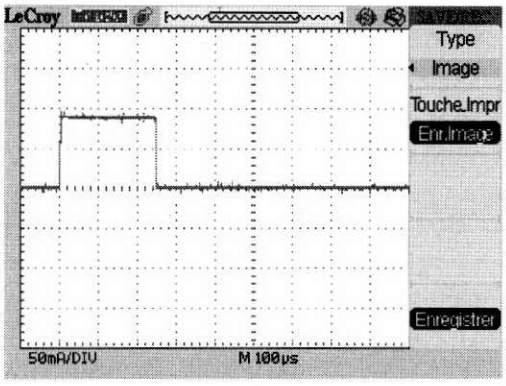
SwissStim Current [mA]



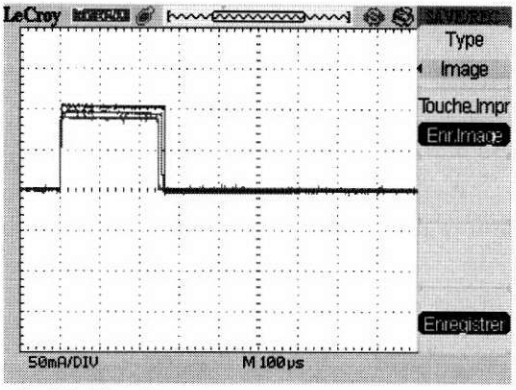
P4 Physio Current [mA]



Hivox Styline Current [mA]



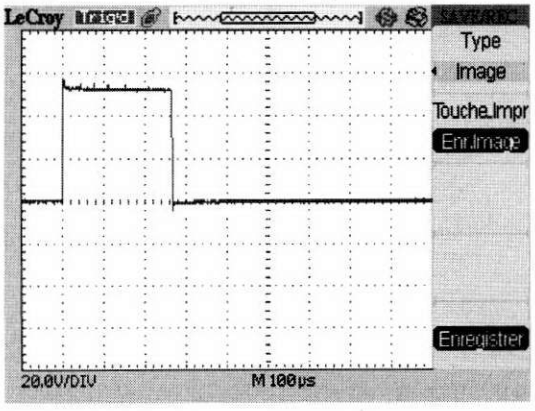
Comparison of All Devices Current [mA]



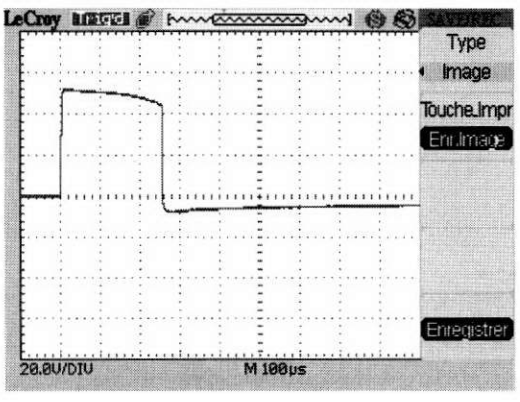
Load:

Load: 2000 ohms

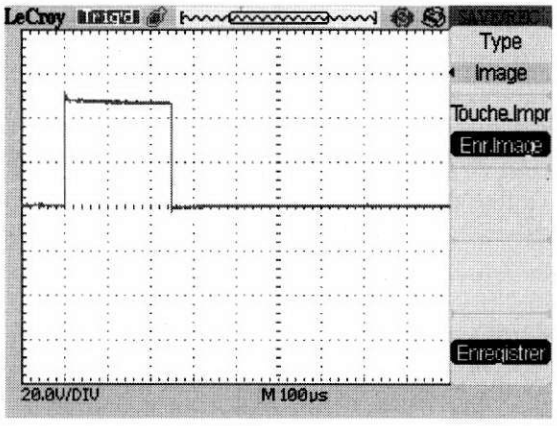
SwissStim Voltage [V]



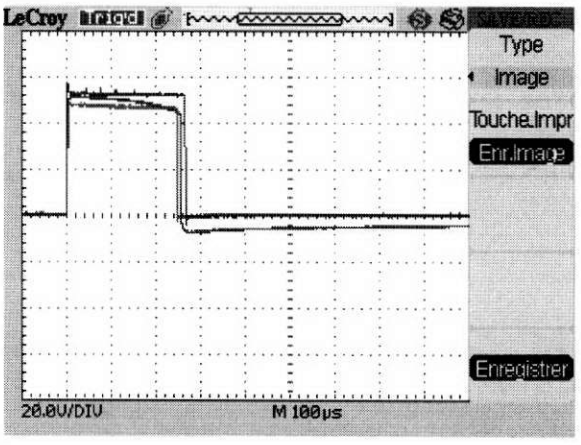
P4 Physio Voltage [V]



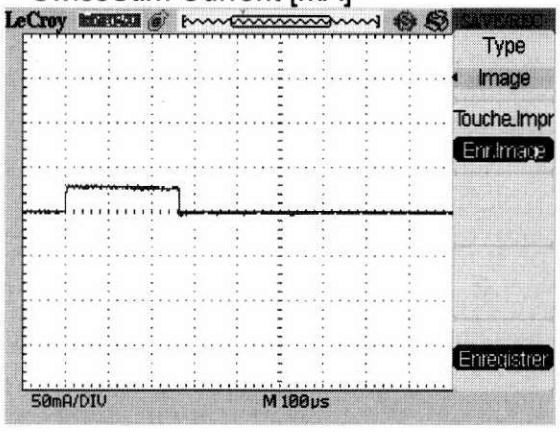
Hivox Styline Voltage [V]



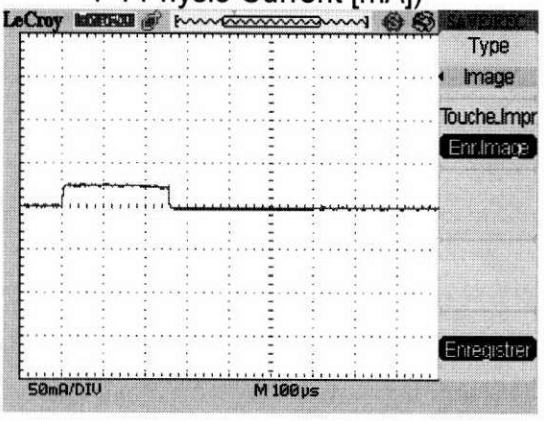
Comparison of All Devices Voltage [V]



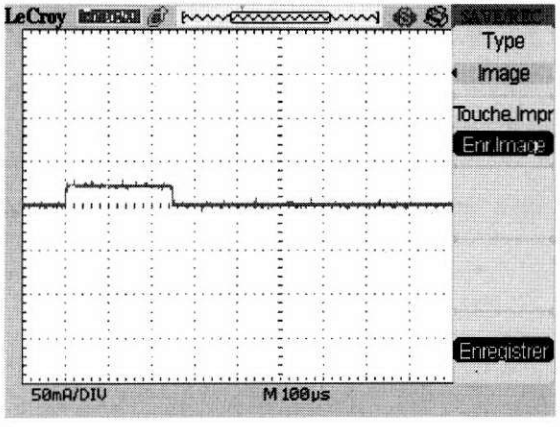
SwissStim Current [mA]



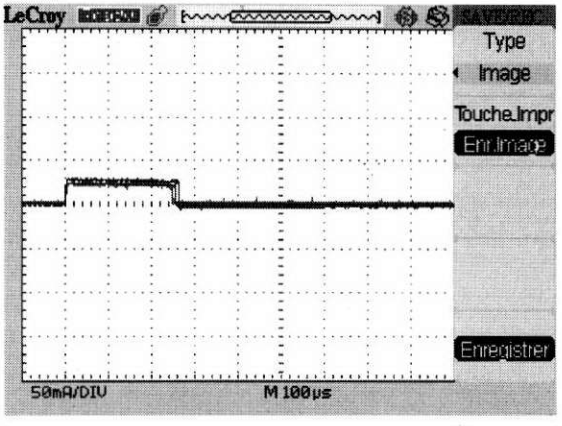
P4 Physio Current [mA])



Hivox Styline Current [mA]

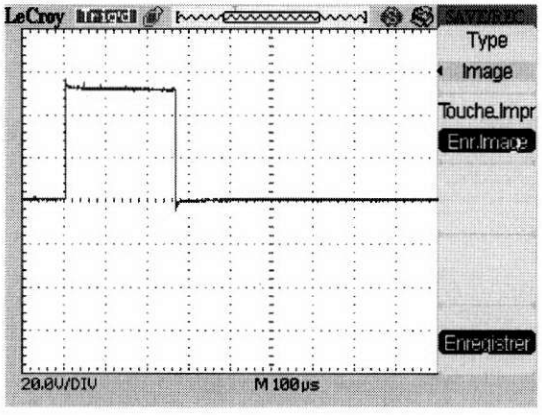


Comparison of All Devices Current [mA]

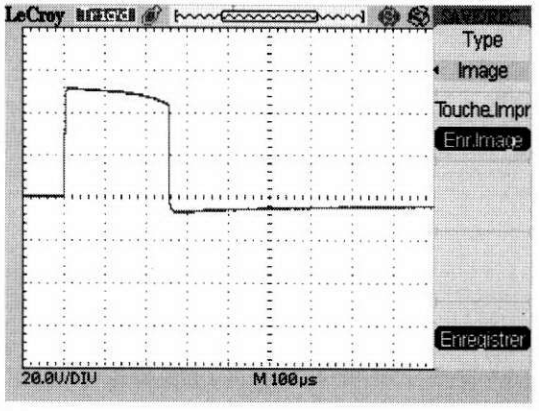


Load: 10000 ohms

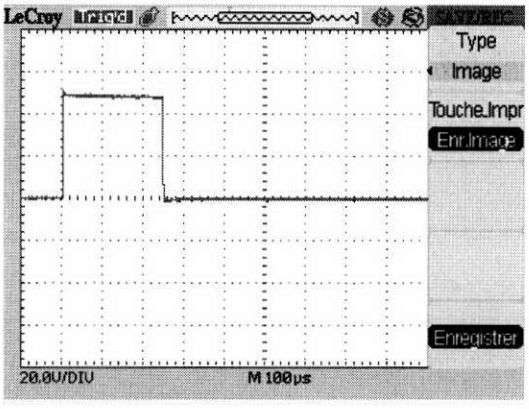
SwissStim Voltage [V]



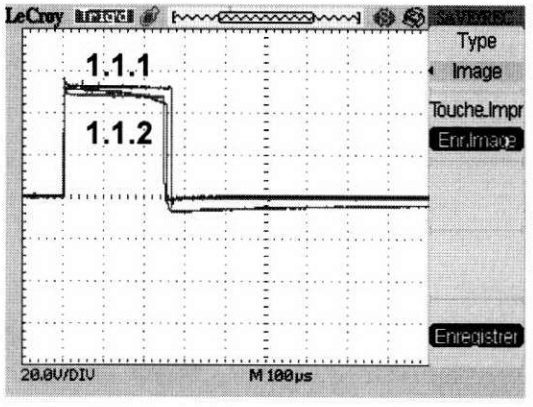
P4 Physio Voltage [V]



Hivox Styline Voltage [V]



Comparison of All Devices Voltage [V]



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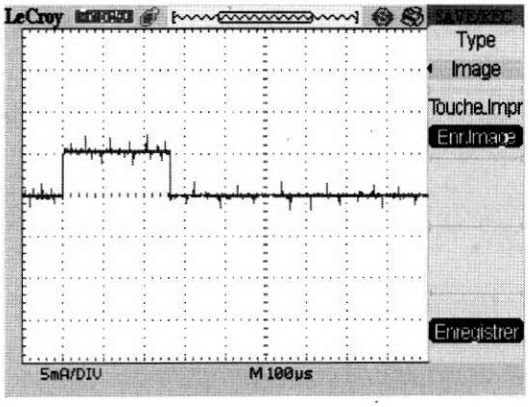
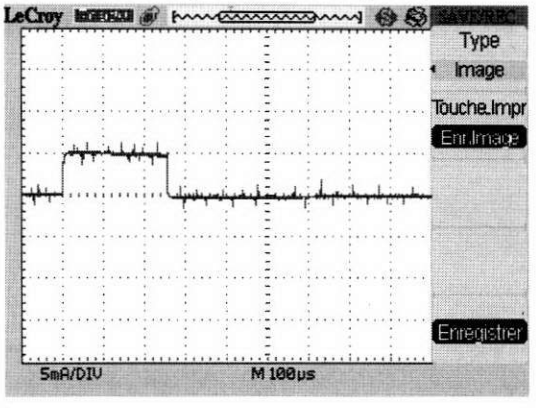
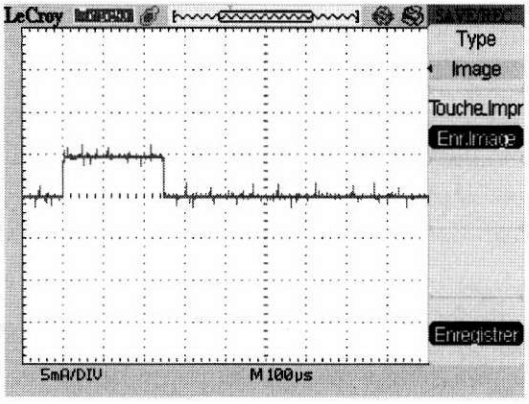


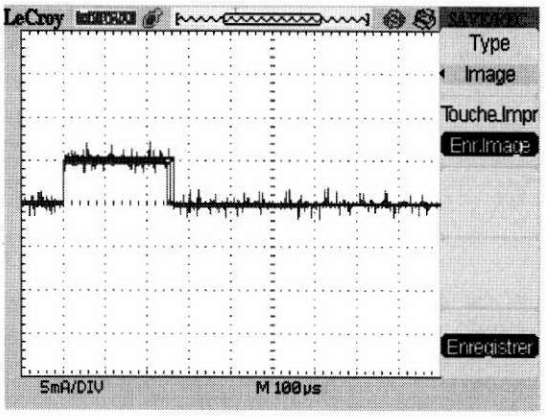
P4 Physio Current [mA]



Hivox Styline Current [mA]



Comparison of All Devices Current [mA]



Other characteristics such as Indications for Use, safety, efficacy and operational parameters of the predicate devices and the ***SWISS$_{STIM}$*** are shown below.

Critical Parameter Comparison Table			
Parameter	***SWISS$_{STIM}$***	**Styline 882**	**P4 Physio**
	K112148	**K092448**	**K022175**
Indications for Use	EMS: ➢ Prevention or retardation of muscle disuse atrophy ➢ Relaxation of muscle spasms ➢ Increasing local blood circulation ➢ Muscle re-education ➢ Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis ➢ Maintaining or improving range of motion of extremities TENS: ➢ Symptomatic relief and management of chronic, intractable pain, and ➢ Adjunctive treatment for post-surgical and post-trauma acute pain	EMS: ➢ Prevention or retardation of muscle disuse atrophy ➢ Relaxation of muscle spasms ➢ Increasing local blood circulation ➢ Muscle re-education and strengthening ➢ Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis ➢ Maintaining or improving range of motion of extremities TENS: ➢ Symptomatic relief and management of chronic, intractable pain, and ➢ Adjunctive treatment for post-surgical and post-	EMS: ➢ Prevention or retardation of muscle disuse atrophy ➢ Relaxation of muscle spasms ➢ Increasing local blood circulation ➢ Muscle re-education and strengthening ➢ Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis ➢ Maintaining or improving range of motion of extremities

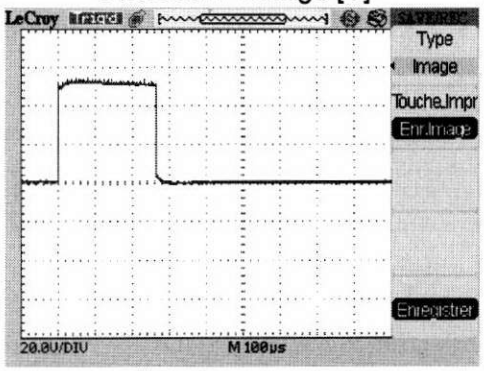
		trauma acute pain	
Safety	1- Complies with ISO 9001/2000 and ISO 13485/2003, International Quality Standard, IEC-601-2-10 European Safety Standard and in compliance with all EC medical device directives applicable to Class IIA medical devices. 2 - Automatic limitation of stimulation current density 3 - Embedded programs cannot be changed; users can only modify the intensity of stimulation 4 - All programs begin with minimal electrical intensity; the medical professional or patient must increase the intensity to desired treatment level 5 - Maximum electrical impulse charge is 50 micro-coulombs 6 - Automatic stimulation current density control precludes excessive current density at the electrode-skin interface, ensuring skin safety 7- Lead cables preclude the possibility of accidental connection to a power source such as an AC power outlet 8 - Specific warnings and contraindications in User Manual	1- Complies with ISO 9001/2000 and ISO 13485/2003, International Quality Standard, IEC-601-2-10 European Safety Standard and in compliance with all EC medical device directives applicable to Class IIA medical devices. 2 – No automatic limitation of stimulation current density 3 – Users can design individual programs as well as modify the intensity of stimulation 4 - All programs begin with minimal electrical intensity; the medical professional or patient must increase the intensity to desired treatment level 5 - Maximum electrical impulse charge is not provided 6 – No automatic stimulation current density control 7- Lead cables preclude the possibility of accidental connection to a power source such as an AC power outlet 8 - Specific warnings and contraindications in User Manual	1- Complies with ISO 9001/2000 and ISO 13485/2003, International Quality Standard, IEC-601-2-10 European Safety Standard and in compliance with all EC medical device directives applicable to Class IIA medical devices. 2 - Automatic limitation of stimulation current density 3 - Embedded programs can not be changed; users can only modify the intensity of stimulation 4 - All programs begin with minimal electrical intensity; the medical professional or patient must increase the intensity to desired treatment level 5 - Maximum electrical impulse charge is 23 micro-coulombs 6 - Automatic stimulation current density control precludes excessive current density at the electrode-skin interface, ensuring skin safety 7- Lead cables preclude the possibility of accidental connection to a power source such as an AC power outlet 8 - Specific warnings and contraindications in User Manual 8 - FDA cleared as safe

Efficacy	The EMS programs are substantially equivalent to the EMS programs in the P4 Physio. The 10 TENS programs are designed to parallel the TENS programs in the predicate device. There are variations but these relate to stimulation patterns rather than frequency ranges.	There are 10 EMS and 10 TENS programs	FDA cleared with 4 EMS programs that have six (6) Indications for Use, including: • Relaxation of muscle spasms • Prevention or retardation of disuse atrophy • Increasing local blood circulation • Muscle re-education • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, and • Maintaining or increasing range of motion
Operation	**Ease of Use**: Only selection of programs, phases and intensity levels are possible; intensity levels are set independently for each channel. Pre-treatment preparation and post-treatment instructions are the same as those for both predicate devices.	**Ease of Use**: User's have additional options and can select not only programs and intensity levels but also program duration time and pulse rates (HZ). These features make this predicate device more complex to operate.	**Ease of Use**: Only selection of programs, phases and intensity levels are possible.

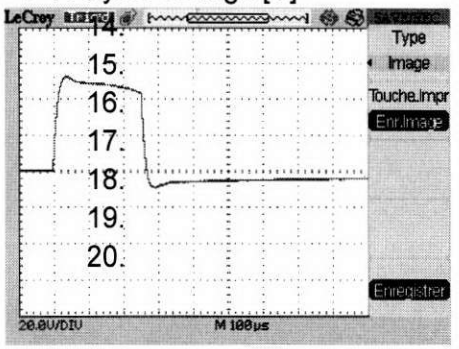
13. Non-Clinical Performance Data

The ***SWISS$_{STIM}$*** device (and predicate devices) have also been analyzed in accordance with the AAMI/ANSI standard "AAMI NS4:1986/(R)2009: AAMI Standard for Transcutaneous Electrical Nerve Stimulators" Electrode/Skin Impedance Model (ESIM)

SwissStim Voltage [V]

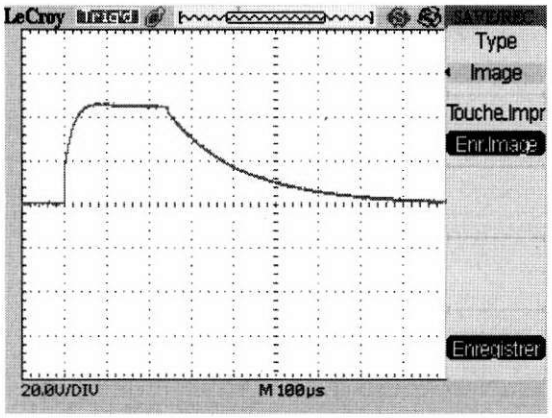


P4 Physio Voltage [V]

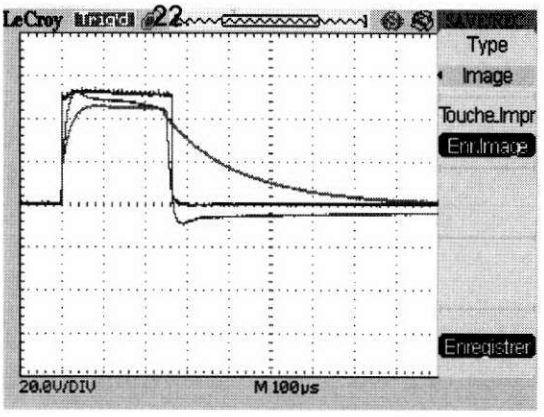


21.

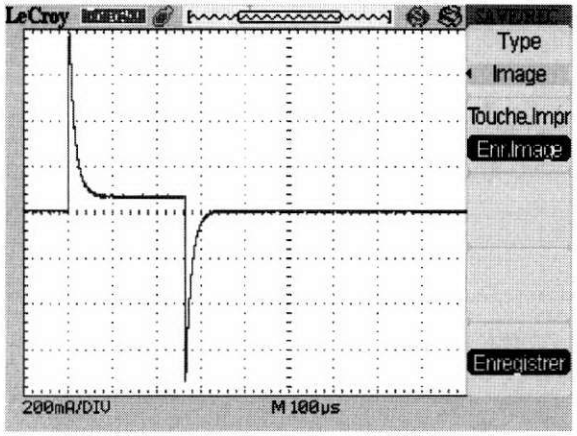
Hivox Styline (Voltage [V], load: ESIM)



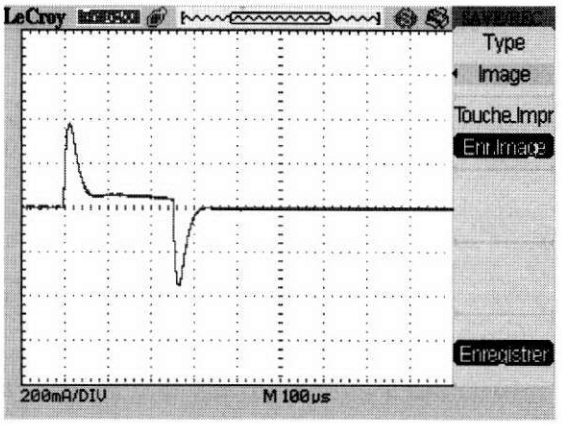
Comparison of All Devices
(Voltage [V], load: ESIM)

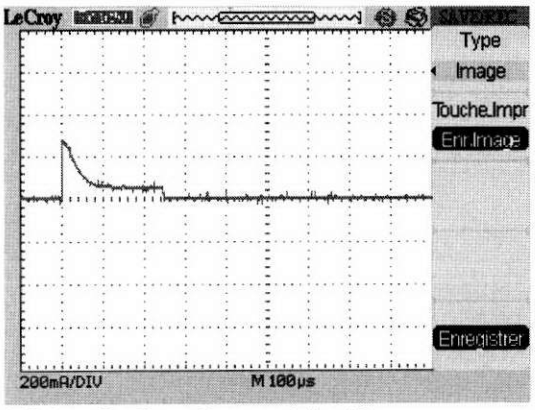


P4 Physio Current [mA]

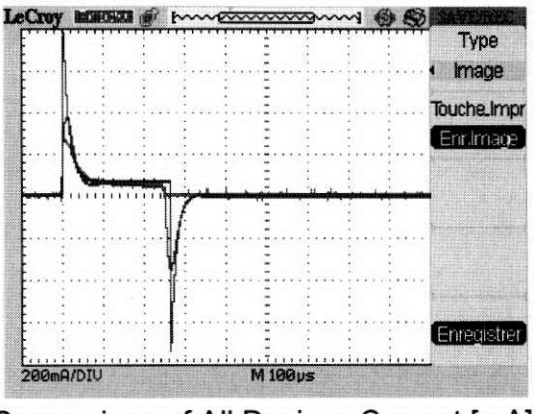


SwissStim Current [mA]





HiVox Styline Current [mA]



Comparison of All Devices Current [mA]

14. Device Safety

The ***SWISS***$_{STIM}$ device is as safe and effective, and functions in substantially equivalent manner to the predicate devices cited in Section C9, above.

This device is manufactured in accordance with ISO 9001/2000 and ISO 13485/2003, International Quality Standard, IEC-601-2-10 European Safety Standard and in compliance with all EC medical device directives applicable to Class IIA medical devices.

Valmed, S.A. has never received notification of any adverse safety events related to any Valmed stimulator devices.

The ***SWISS***$_{STIM}$ is designed so that even improper or accidental application of the stimulator will not produce cardiac rhythm disturbances (this does not apply to persons who have implanted cardiac pacemakers). This safety factor is due to the minimal electrical charge of the stimulating impulses, which, under all conditions, do not exceed 50 microcoulombs. The effective value of the stimulation voltage a person will experience during treatment with the ***SWISS***$_{STIM}$ is very low, below 7 volts (root mean square) at maximum setting.

A significant safety feature of the ***SWISS***$_{STIM}$ (and the P4 Physio) is automatic limitation of stimulation current density on the skin under the electrodes. (i.e., electrical energy delivered per square centimeter) Due to the voltage-source output circuitry, the ***SWISS***$_{STIM}$ presents minimal risk of skin burns. The skin current densities of Valmed stimulators are, at all times, well below the safe limit of 2 milliamperes (mA) per square centimeter, as required by the IEC 601-2-10 standard. The skin burn hazards caused by many electrostimulators have been widely reported in medical literature and by the FDA. These hazards are minimal in the ***SWISS***$_{STIM}$ due to the electronic circuit design incorporated in the output amplifier of the device (a voltage source generator similar to that used in implantable cardiac pacemakers).

Specific safety features include:

a. It is not possible for users to modify the embedded programs; users can only modify the intensity of stimulation
b. All programs begin with minimal electrical intensity; the medical professional or patient must increase the intensity to his/her desired treatment level.
c. Maximum possible electrical impulse charge is 50 microcoulombs.
d. Automatic control of stimulation current density, thus precluding excessive current density at the electrode-skin interface and ensuring skin safety.
e. The connector plug precludes the possibility of accidental connection to a power source such as an AC power outlet.
f. Specific warnings and contraindications in User Manual.

All device accessories also meet safety standards; 510(k) cleared electrodes are specified (K872976) and supplied with this device.

15. Electromagnetic Compatibility and Electrical Safety

FDA recommended testing has been completed, as follows:

Test		Standards	Result
Emission	EN 55011	EN 60601-1-2/EN 60601-2-10	Pass
Immunity to Electrical Discharge	EN 61000-4-2	EN 60601-1-2/EN 60601-2-10	Pass
Immunity to Radiated rf/emf	EN 61000-4-3	EN 60601-1-2/EN 60601-2-10	Pass
Immunity to Conducted Disturbances Induced by rf Fields	EN 61000-4-6	EN 60601-1-2/EN 60601-2-10	Pass
Immunity to Power Frequency Magnetic Field	EN 61000-4-8	EN 60601-1-2/EN 60601-2-10	Pass

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Valmed, S.A.
% Mr. Carl Magnell
Official Correspondent
Ave du Tourbillion 34
1950 Sion, Valis
Switzerland

APR 30 2012

Re: K112148
Trade/Device Name: Powered Muscle Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ
Dated: April 16, 2012
Received: April 19, 2012

Dear Mr. Magnell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

VALMED
SWISS TECHNOLOGY

A. Indications for Use

510(k) Number: K112148

Device Name: Powered Muscle Stimulator

Indications for EMS use are:
- Prevention or retardation of muscle disuse atrophy
- Relaxation of muscle spasms
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or improving range of motion of extremities

Indications for TENS use are:
- Symptomatic relief and management of chronic, intractable pain, and
- Adjunctive treatment for post-surgical and post-trauma acute pain

Prescription Use **X** (Part 21 CFR 801 Subpart D	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112148